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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/646,624	09/20/2000	Claudine Elvire Marie Bruck	BC45203	2480

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EXAMINER	
BLANCHARD, DAVID J	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 04/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/646,624	BRUCK ET AL.	
	Examiner	Art Unit	
	David J Blanchard	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 29-58 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 29-58 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

To have a general inventive concept under PCT rule 13.1, the inventions need to be linked by a special technical feature. The special technical feature recited in claim 1 is a polypeptide, which is at least 90% identical to SEQ ID NO:2 and immunogenic fragments at least 90% identical to an aligned contiguous segment of SEQ ID NO:2. In view of this Hillier et al (EMBL Database entry HS1237334, Accession No. AA436049, 6/1/1997) reads on the claim. Hillier et al teaches a polypeptide that shares 100% identity to an aligned contiguous segment of SEQ ID NO:2 (see the attached alignment). Therefore the technical feature recited in claim 1 is not special. Accordingly the groups are not so linked as to form a single general concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 29-36, drawn to a polypeptide, which is at least 90% identical to SEQ ID NO:2 and immunogenic fragments at least 90% identical to an aligned contiguous segment of SEQ ID NO:2.

Group II, claims 37-42, drawn to a polynculeotide encoding a polypeptide which is at least 90% identical to SEQ ID NO:2 and immunogenic fragments at least 90% identical to an aligned contiguous segment of SEQ ID NO:2, a vector, host cells and a method of producing said polypeptide.

Group III, claims 43-47, drawn to a polynucleotide sequence of SEQ ID NO:1 and full complements, a vector and host cell comprising said polynucleotide and a method of producing the isolated polypeptide encoded by SEQ ID NO:1.

Group IV, claims 48-51, drawn to a vaccine comprising a polypeptide, which is at least 90% identical to SEQ ID NO:2 and immunogenic fragments at least 90% identical to an aligned contiguous segment of SEQ ID NO:2.

Group V, claim 52, drawn to a method for inducing an immune response in a mammal with a polypeptide, which is at least 90% identical to SEQ ID NO:2 and immunogenic fragments at least 90% identical to an aligned contiguous segment of SEQ ID NO:2.

Group VI, claim 53, drawn to a method for screening to identify compounds which stimulate or inhibit the function of a polypeptide, which is at least 90% identical to SEQ ID NO:2 and immunogenic fragments at least 90% identical to an aligned contiguous segment of SEQ ID NO:2.

Group VII, claims 54-55, drawn to a method for treating ovarian or colon cancer with a polypeptide, which is at least 90% identical to SEQ ID NO:2 and immunogenic fragments at least 90% identical to an aligned contiguous segment of SEQ ID NO:2.

Group VIII, claim 56, drawn to a process for diagnosing a disease with a polypeptide, which is at least 90% identical to SEQ ID NO:2 and immunogenic fragments at least 90% identical to an aligned contiguous segment of SEQ ID NO:2.

Group IX, claim 57, drawn to a polypeptide, which is at least 90% identical to SEQ ID NO:4 or immunogenic fragments at least 90% identical to an aligned contiguous segment of SEQ ID NO:4.

Group X, claim 58, drawn to a polynucleotide encoding a polypeptide, which is at least 90% identical to SEQ ID NO:4 or immunogenic fragments at least 90% identical to an aligned contiguous segment of SEQ ID NO:4.

2. The inventions listed as Groups I-X do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: As set forth above, in view of the teaching of Hillier et al the groups are not so linked as to form a single

general concept under PCT Rule 13.1 because the technical feature of claim 1 is not special.

Inventions of Groups I-IV and IX-X represent separate and distinct products, which are made by materially different methods, and are used in materially different methods, which have different modes of operation, different functions and different effects. The expression cassettes and host cells of Groups II, III and X and the polypeptides of Groups I and IX and the vaccine of Group IV are all structurally and chemically different from each other. The polynucleotides are made by nucleic acid synthesis while the polypeptide is made by translation of mRNA. Furthermore, the polynucleotide/expression cassettes can be used for hybridization screening and the polypeptides can be used to raise antibodies, for example. The inventions of Groups II, III and X all require different polynucleotide sequences, which encode different polypeptides and are not required on for the other. The inventions of Groups I and IX require different polypeptide sequences and the sequence of SEQ ID NO:2 is not required by Group IX and the sequence of SEQ ID NO:4 is not required by Group I. Further, art on one sequence would not necessarily be art on the other sequence. The examination of all groups would require different searches in the U.S. Patent shoes and the scientific literature and would require the consideration of different patentability issues. Thus, the inventions of Groups I-IV and IX-X are patentably distinct.

The methods of Inventions V-VIII differ in the method objectives, method steps and parameters and in the reagents used. Invention III recites a method for inducing an immune response in a mammal with a polypeptide, which is at least 90% identical to

SEQ ID NO:2 and immunogenic fragments at least 90% identical to an aligned contiguous segment of SEQ ID NO:2; Invention VI recites a method for screening to identify compounds which stimulate or inhibit the function of a polypeptide, which is at least 90% identical to SEQ ID NO:2 and immunogenic fragments at least 90% identical to an aligned contiguous segment of SEQ ID NO:2; Invention VII recites a method for treating ovarian or colon cancer with a polypeptide, which is at least 90% identical to SEQ ID NO:2 and immunogenic fragments at least 90% identical to an aligned contiguous segment of SEQ ID NO:2; Invention VIII recites a process for diagnosing a disease with a polypeptide, which is at least 90% identical to SEQ ID NO:2 and immunogenic fragments at least 90% identical to an aligned contiguous segment of SEQ ID NO:2. The examination of all groups would require different searches in the U.S. Patent shoes and the scientific literature and would require the consideration of different patentability issues. Thus Inventions V-VIII are separate and distinct in having different method objectives, method steps and different endpoints and are patentably distinct.

Inventions I and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide of Group I can be used in a materially different method such as the materially different methods of Groups VI-VIII in addition to the method of Group V.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and different searches in the patent literature, restriction for examination purposes as indicated is proper.

4. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See

"Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Blanchard whose telephone number is (571) 272-0827. The examiner can normally be reached at (571) 272-0827 from 8:00 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached at (571) 272-0871.

Official papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The official fax number for Group 1600 where this application or proceeding is assigned is (703) 872-9306.

Respectfully,
David J. Blanchard
571-272-0827

LARRY R. HELMS, PH.D
PRIMARY EXAMINER